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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,315	10/03/2003	Kyu Won Kim	123034-05004738	9469

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LOWE HAUPTMAN HAM & BERNER, LLP
1700 DIAGONAL ROAD
SUITE 300
ALEXANDRIA, VA 22314

EXAMINER	
FORMAN, BETTY J	

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1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/677,315	KIM ET AL.
	Examiner	Art Unit
	BJ Forman	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2007*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-13* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *9-13* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed 31 July 2007 in which the specification and claims 9 and 10 were amended. The amendments have been thoroughly reviewed and entered. The previous objection to the specification is withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b) and/or 103 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 9-13 are under prosecution.

Claim Objections

2. Claim 10 is objected to because of the following informalities: DNA is misspelled "DNS". Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meade (U.S. Patent No. 6,248,229, issued 19 June 2001) in view of Sorge (U.S. Patent No. 7,183,052,

filed 17 July 2007) or Ullman et al (U.S. Patent Application Publication No. 2003/0152924, filed 7 December 2001).

Regarding Claims 9-10, Meade discloses a method of DNA detection comprising, immobilizing a binding ligand and hybridizing a binding partner labeled with an electrochemically active compound (Column 17, lines 26-40) and wherein the binding partner is complementary to the target DNA (Column 24, lines 30-41), adding the target to the binding partner-binding ligand to derive a competitive reaction between the binding ligand and the target and detecting amount and type of DNA by measuring a current change in the electrochemical signal before and after the competitive reaction (e.g. decreased signal, Column 24, lines 38-41) and wherein the detection is via a change in current (Columns 20-23, especially, Column 21, lines 25-43).

Meade specifically states that the target is detected following target competition for the binding partner (Column 24, lines 38-41). The favored hybridization and target detection of Meade would require favored complementation between the target and binding partner. Meade teaches the method wherein the binding partner is disassociated from the binding ligand, but does not specifically teach forming a double strand hybrid by applying heat to facilitate the dissociation of the binding partner and binding ligand followed by subsequent cooling.

However, heating and cooling to facilitated target detection during competitive hybridization between complementary probes was well known in the art at the time the claimed invention was made as taught by Ullman and Sorge.

Sorge teach a similar method of DNA detection comprising immobilizing complementary probe DNA and signaling DNA, adding a target DNA to derive a competitive reaction between the probe and target, heating near the melting temperature of the probe-signal hybrid and cooling to form a target-signal hybrid which is then detected (Column 4, lines 28-60; Column 10, lines 14-48; and Examples 2-4). Sorge further teach the probes are designed to dissociated under repeated heating and cooling conditions (e.g. PCR) to facilitate probe-target binding (Column 13, lines 50-Column 14, line 15, Examples 2-4).

Ullman also teach a similar method of DNA detection comprising providing complementary probe DNA and signaling DNA, adding a target DNA to derive a competitive reaction between the probe and target, heating near the melting temperature of the probe-signal hybrid and cooling to form a target-signal hybrid which is then detected (e.g. ¶ 105).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the heating and cooling cycles of Sorge and Ullman to the competitive hybridization of Meade. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the well known, routinely practiced and preferred use of heating and cooling taught by Sorge and Ullman.

Regarding Claim 11, Meade discloses the method wherein the amount of target is quantified by measuring a change in signal before and after the competitive reaction (Column 21, lines 25-43).

Regarding Claim 12, Meade does not teach the probes correspond to several types of expected target sequence. However, Ullman teaches the similar method wherein the type of DNA is determined by a competitive reaction between a plurality of allele-specific probe DNA/signaling DNA hybrids and target and measuring a signal to identify the target (¶ 169-171) and Sorge teach the similar method wherein the type of DNA is determined by a competitive reaction between a plurality of allele-specific probe DNA/signaling DNA hybrids and target and measuring a signal to identify the target (Column 10, line 14-55).

Regarding Claim 13, Meade discloses the method wherein the DNA chip comprises at least two different probe DNAs, each fixed to an electrode of an electrode array (Column 17, lines 26-41).

5. Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al (U.S. Patent No. 6,207,369, issued 27 March 2001) in view of Hill et al (U.S. Patent No. 4,840,893, issued 20 June 1989), (U.S. Patent No. 7,183,052, filed 17 July 2007) and/or Ullman et al (U.S. Patent Application Publication No. 2003/0152924, filed 7 December 2001).

Regarding Claims 9-10, Wohlstadter et al disclose a method for detecting DNA comprising preparing a chip comprising probe DNA fixed to electrodes (Column 89, lines 42-45) wherein the probe DNA hybridizes to signaling DNA wherein probe DNA is also complementary to the target DNA and wherein the signaling DNA is labeled with an electrochemically active compound (i.e. ECL-TAG-a labeled sequences which can compete with the analytes of interest for binding surface immobilized probes, Column 89, lines 49-61), the method further comprises applying target DNA to the surface to derive a competitive reaction among the probe DNA, the signaling DNA and the target DNA and detecting amount and type of target DNA by detecting a change in electrochemical signal (Column 48, lines 13-48).

The comparative complementation recited in Claim 9 is deemed to be inherent in the competition assay of Wohlstadter because if hybridization between the target and binding partner is not favored, the binding partner would remain hybridized to the immobilized binding ligand and the assay would not function to detect the target. Wohlstadter specifically states that the target is detected following target competition for the binding partner (Column 24, lines 38-41). The favored hybridization and target detection of Wohlstadter would require a favored complementation between the target and binding partner.

Wohlstadter teaches that devices for measuring current are used in the method (Column 5, lines 27-34) but does not specifically teach that the changed electrochemical signal is via current measurement. However, current measurements to detect a target was well known in the art at the time the claimed invention was made as taught by Hill et al.

Hill et al teach a similar method for detecting a target comprising a probe + ligand, probe being complementary to the target, a second ligand + electrochemical label and an anti-ligand. The probe-ligand and second ligand are binding partners for the anti-ligand. In the presence of target, the probe-ligand is not available for binding to the anti-ligand, the electrochemically labeled second ligand binds the anti-ligand whereby current is measured to determine the presence of target (Column 2, lines 1-56). Hill et al teaches that the change is current is proportional to the amount of target present and the degree of homologous binding between the probe and target results in a measurable change in current (Column 7, lines 29-58). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the current detection of Hill et al to the target detection of Wohlstadter et al. One of ordinary skill in the art would have been motivated to do so based on the devices suggested by Wohlstadter (Column 5, lines 27-34). One would have been further motivated for the expected benefit of determining the amount of target and degree of homologous binding by simple measurement of current as taught by Hill et al (Column 7, lines 29-58). Wohlstadter et al does not teach repeated heating and cooling.

However, heating and cooling to facilitated target detection during competitive hybridization between complementary probes was well known in the art at the time the claimed invention was made as taught by Ullman and Sorge.

Sorge teach a similar method of DNA detection comprising immobilizing complementary probe DNA and signaling DNA, adding a target DNA to derive a competitive reaction between the probe and target, heating near the melting temperature of the probe-signal hybrid and cooling to form a target-signal hybrid which is then detected (Column 4, lines 28-60; Column 10, lines 14-48; and Examples 2-4). Sorge further teach the probes are designed to dissociated under repeated heating and cooling conditions (e.g. PCR) to facilitate probe-target binding (Column 13, lines 50-Column 14, line 15, Examples 2-4).

Ullman also teach a similar method of DNA detection comprising providing complementary probe DNA and signaling DNA, adding a target DNA to derive a competitive reaction between the probe and target, heating near the melting temperature of the probe-signal hybrid and cooling to form a target-signal hybrid which is then detected (e.g. ¶ 105).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the heating and cooling cycles of Sorge and Ullman to the competitive hybridization of Wohlstadter et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the well known, routinely practiced and preferred use of heating and cooling taught by Sorge and Ullman.

Regarding Claim 11, Wohlstadter et al disclose the method wherein the amount of target DNA is quantified by measuring a change before and after the competitive reaction (Column 49, lines 19-22).

Regarding Claim 12, Wohlstadter et al disclose the method wherein the type of DNA is determined by a competitive reaction between double strands of probe DNA/signaling DNA and an unknown target and measuring a signal produced from the competitive reaction on an electrode array (Fig. 42, Example 6.35-6.37, Column 89, line 19-Column 91, line 20).

Regarding Claim 13, Wohlstadter et al disclose the method wherein multiple DNA detection is performed using the chip having double strands of probe DNA/signaling DNA to each electrode of an electrode array (Fig. 42, Example 6.35, Column 89, lines 19-62).

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
September 21, 2007